

MINUTES OF THE 176th MEETING OF THE REVIEW COMMITTEE ON GENETIC MANIPULATION (RCGM) HELD ON 11.10.2019 IN THE DEPARTMENT OF BIOTECHNOLOGY

The Chairman, RCGM extended a formal welcome to the members of the RCGM for the 176th meeting and initiated the process of the meeting. The list of participants is given as Annexure-I.

2. The Committee adopted the minutes and recommendations of the 175th meeting of the RCGM held on 11.09.2019.

3. On action taken report, the Member-Secretary informed that during 175th meeting of the RCGM, a total of 120 applications including information items were considered and the Secretariat is in the process of issuing permit letters based on the recommendations of the RCGM.

4. Proposals considered

4.1 Applications in the area of Pharmaceuticals

The Committee considered applications to import recombinant Insulin glargine, and recombinant human insulin; to receive Denosumab drug product; to conduct pre-clinical toxicity study for Romiplostim biosimilar and Ranibizumab biosimilar. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

4.2 Applications in the area of Agriculture

The Committee considered application to obtain approval on biosafety protocols related to purified *Cry1F* protein. After deliberation on each application including information items, appropriate decision was taken by the RCGM.

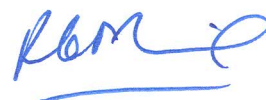
4.3 Other items

The Committee considered “Genetically Engineered (GE) plants Containing Stacked Events” and “Environmental Risk Assessment (ERA) of Genetically Engineered Microorganisms (GEM) for Environmental Release Purposes”, constitution of Expert committee to develop draft document on biosafety and biosecurity issues arising from the research and environmental release of GE insects, constitution of a sub-committee to review the draft “Handbook for Institutional Biosafety Committees (IBSC), 2019”, revision of permit letter for storage of transgenic maize seeds and appropriate decision was taken by the RCGM.

The next meeting of the RCGM was scheduled on 11.11.2019.

No other transaction took place and the meeting ended with vote of thanks to the Chair.

The minutes are approved.



(Dr. Rakesh Kumar Mishra)
Chairman, RCGM

List of Participants:

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| 1. Dr. Rakesh Kumar Mishra, Director CCMB, Hyderabad | - Chairman |
| 2. Dr. Pradhyumna K. Singh, CSIR-NBRI, Lucknow | - Member |
| 3. Dr. Gururaj Katti, Principal Scientist, IIRR, Hyderabad | - Member |
| 4. Dr. (Mrs.) Chandish R. Ballal, Director- NBAIR, Bangalore | - Member |
| 5. Dr. R. Uma Shanker, UAS Bengaluru | - Member |
| 6. Dr. S.K. Rath, Principal Scientist, CSIR-CDRI, Lucknow | - Member |
| 7. Dr. Rajnish Kumar Chaturvedi, CSIR-IITR, Lucknow | - Member |
| 8. Dr. P.V. Mohanan, Scientist G, SCTIMST, Kerala | - Member |
| 9. Dr. K.G. Tirumurugan, TANUVAS, Chennai | - Member |
| 10. Dr. Shilpi Paul, DST, New Delhi | - Nominee, DST |
| 11. Dr. R. Chandrashekhar, CDSCO | - Nominee, CDSCO |
| 12. Dr. Alka Sharma Scientist-G, DBT | - Member |
| 13. Dr. Vanga Siva Reddy, CSO, BSU, New Delhi | - Special Invitee |
| 14. Dr. Nitin Jain, Scientist-F, DBT | - Member Secretary |
| 15. Dr. Gandharva Nagpal | - Scientist C, DBT |

Biosafety Support Unit:

16. Dr. Sangeeta Agarwal, Chief (Agriculture)
17. Dr. Reema Sharma, Scientist

Other representatives:

18. Satish Panchal, Sun Pharmaceutical Industries Ltd., Ahmedabad
19. Ravishankara, Sun Pharmaceutical Industries Ltd., Ahmedabad
20. Srinivas Reddy, Sun Pharmaceutical Industries Ltd., Ahmedabad
21. Jatin Vimal, Levim Biotech LLP, Chennai
22. Srikar Raman, Levim Biotech LLP, Chennai
23. Kadlamani Krishnan, Levim Biotech LLP, Chennai
24. Nagraj Kampte, Metahelix Life Sciences Ltd., Bangalore
25. Mahesh Gupta, Metahelix Life Sciences Ltd., Bangalore